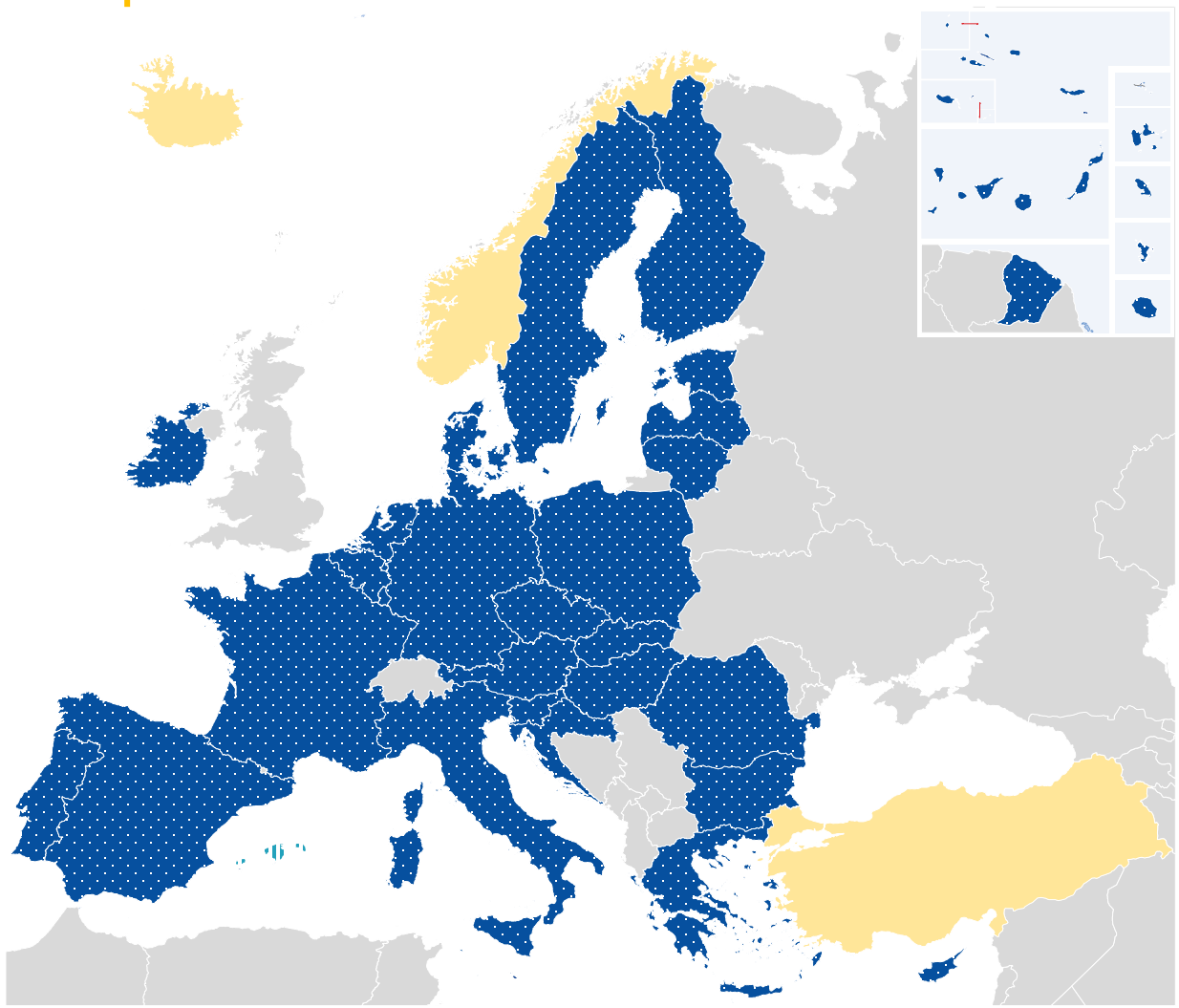
Regulatory Update from European Commission - EU

Nada Alkhayat
Policy Officer, Medical Devices
European Commission – DG Health & Food Safety
March 12, 2024

IMDRF International Medical Device Regulators Forum

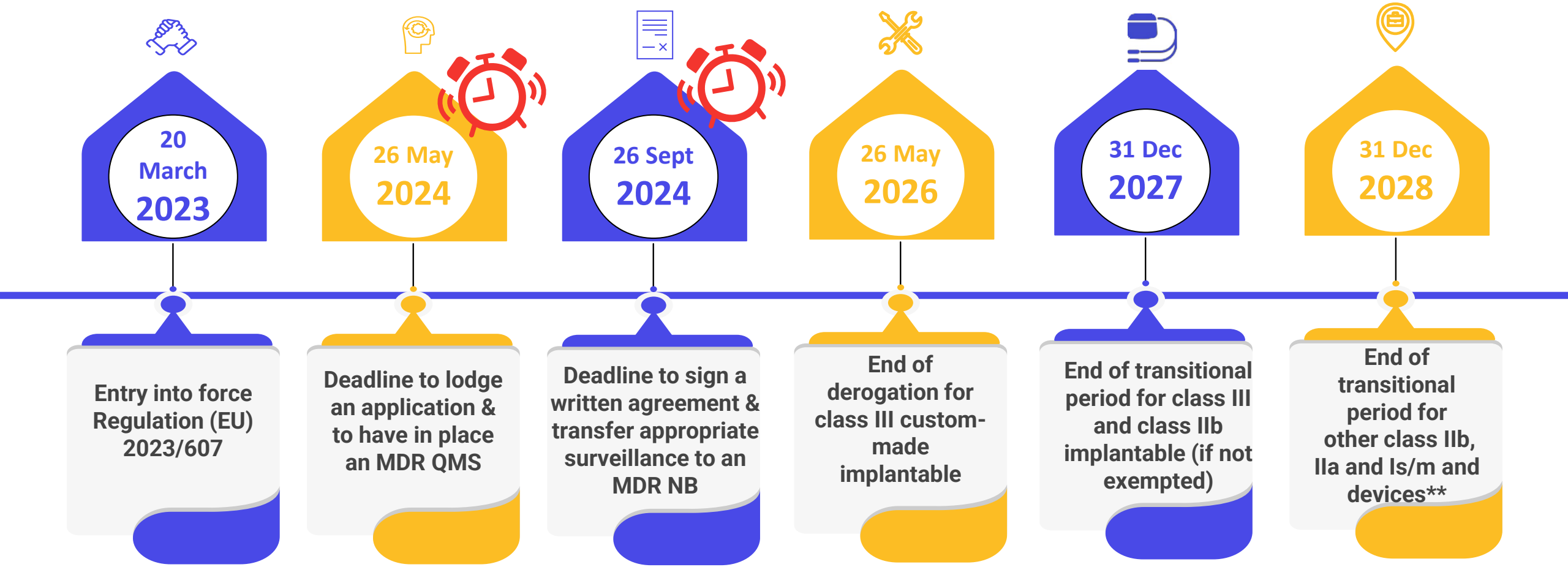
The EU 27 Member State Competent Authorities for Medical Devices



+ EEA & CUA:

IMDRF International Medical Device Regulators Forum

MDR transitional period



* For devices that did not require involvement of a NB under MDD (e.g. Ir)

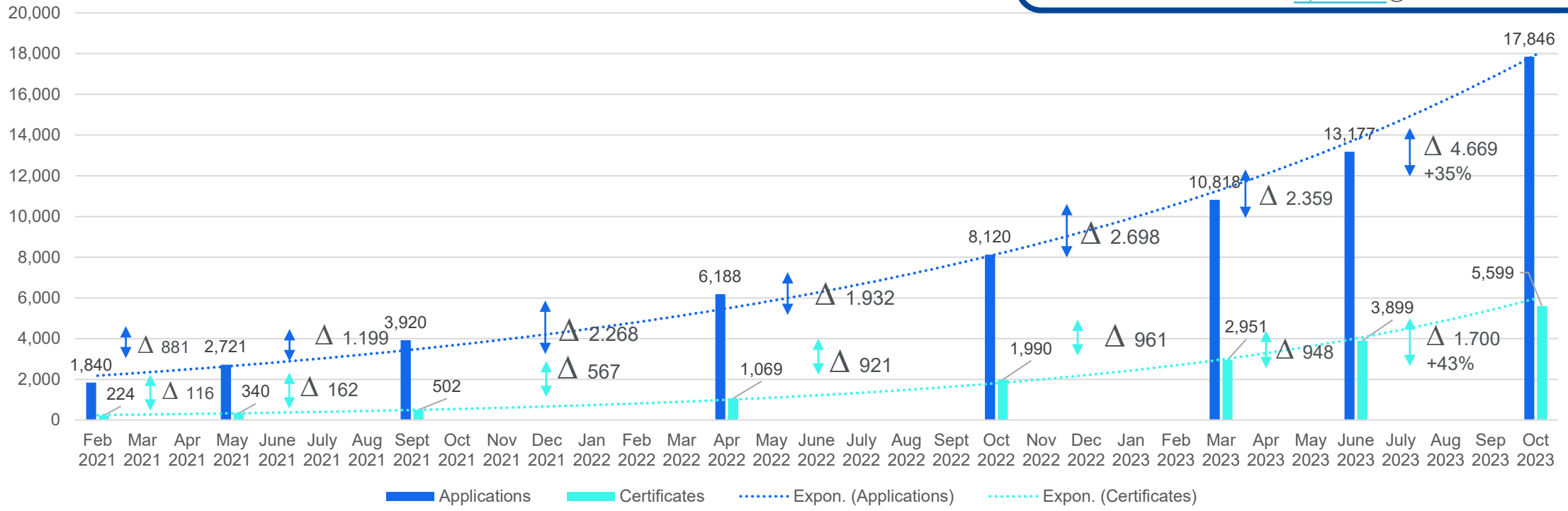
MDR applications filed and certificates issued

MD

October 2023

MDR Applications:
Total number of applications filed by Annex Ⓜ: 17.846*

MDR Certificates:
Total number of certificates by Annex Ⓜ: 5.599



Notes: October 2023: Designated NBs for MD: 39; NBs that included Annex XVI products in the numbers provided: 15

* The data shown comes from the medium data set Ⓜ – except for 2 NBs where the total number of applications filed was derived from the small data set Ⓢ since they could not provide the data per Annex.

- Δ (Delta) = Difference in MDR Applications / MDR Certificates from one survey to the next one
- **Applications filed**: This number includes **all applications filed (syn. lodged) so far** according to MDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 31/10/2023), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing MDR certificates. Pre-application activities are not included. One application can correspond to more than one certificate.
- **Certificates issued:** This number includes **certificates issued so far** (from designation up to 31/10/2023) under the MDR.

IMDRF International Medical Device Regulators Forum

Commission proposal 2024/0021 - Objectives and means

1

Ensure availability especially of high-risk in vitro diagnostics (IVDs) by extending transition periods

2

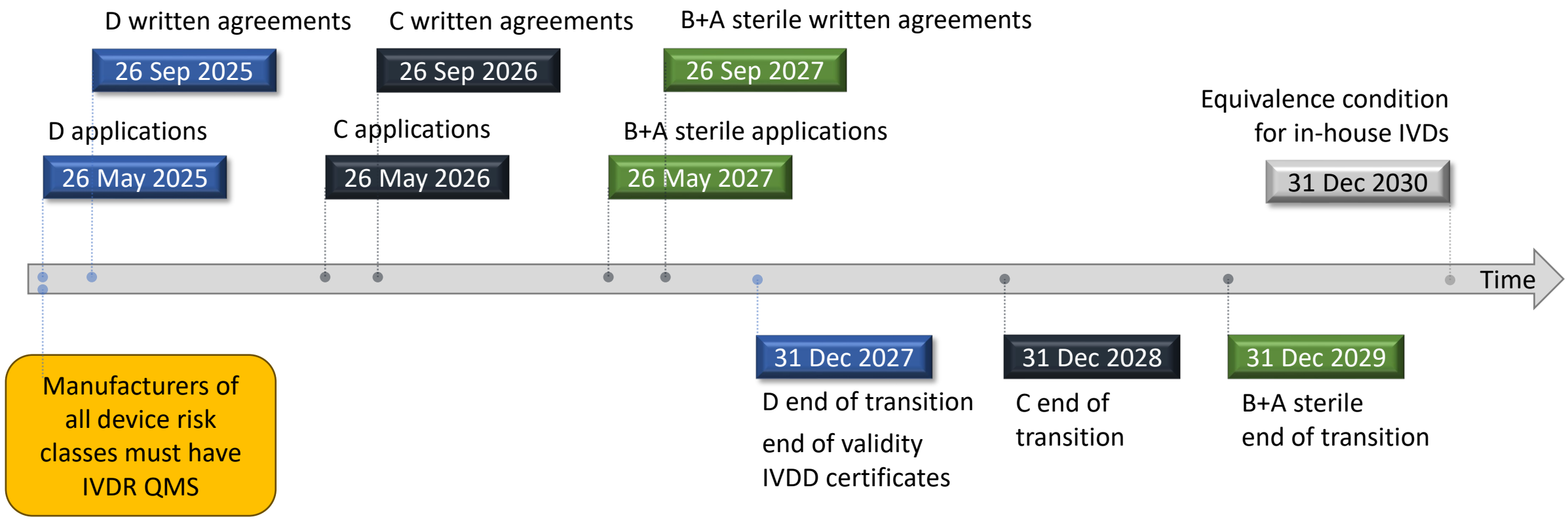
Provide healthcare systems **more time to safeguard patients care** by introducing advance warning of interruptions of supply of certain medical devices / IVDs

3

Enhance transparency by enabling a gradual roll-out of the European Database on Medical Devices (EUDAMED)

IVDR - Transitional periods

1



Milestones/Conditions

1

- continuous compliance with IVD Directive
- no significant changes
- no unacceptable risk to health/safety
- IVDR compliant QMS in place by 26 May 2025
- applications lodged and written agreements with notified bodies signed by certain staggered deadlines (depending on risk class)

↓

extension of validity of IVD Directive certificates and/or devices can continue be placed on the market

Interruption of supply – prior notice

2

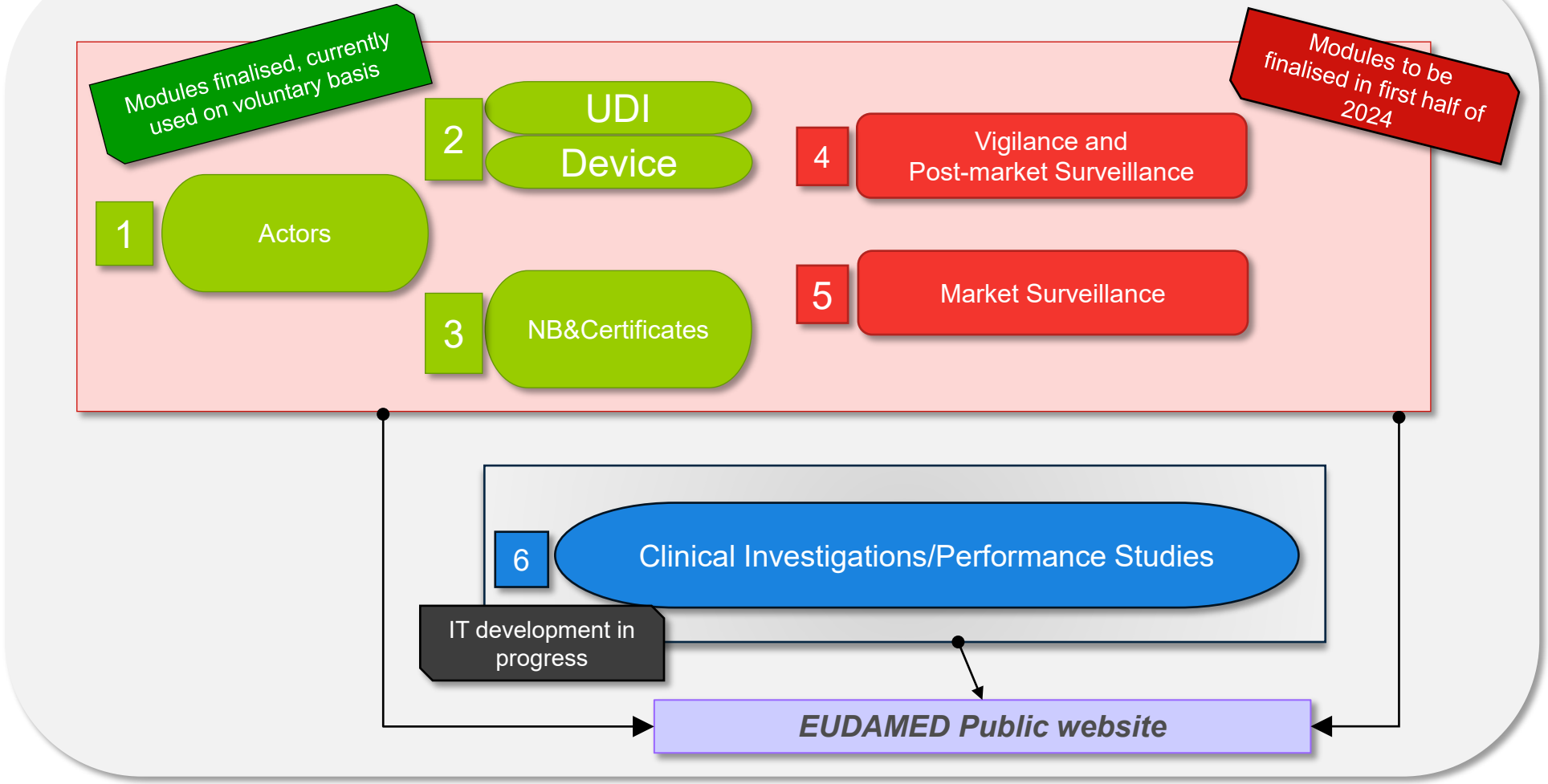
- Prior notice
  - by manufacturer to
    - competent authority where manufacturer/AR is established (+information exchange between CAs)
    - economic operators & health institutions/healthcare professionals to whom they directly supply the device
    - 6 months prior to interruption
  - by economic operators that received notice to
    - other economic operators & health institutions/healthcare professionals to whom they directly supply the device
    - without undue delay

Interruption of supply – prior notice

2

- Interruption of supply of certain medical devices / IVDs (Art. 10a MDR/IVDR)
  - manufacturer anticipates interruption
  - reasonably foreseeable that interruption results in risk of serious harm to patients or public health in one or more Member States
  - rationale/examples (see recital 15)
    - relevance of device for essential healthcare services
    - dependency of patient health & safety
    - absence of suitable alternatives
    - considering:
      - expected length of interruption
      - quantities of devices on the market and available stocks
      - timelines for procuring alternative devices

EUDAMED


Modules finalised, currently used on voluntary basis
Modules to be finalised in first half of 2024
1
Actors
2
UDI
Device
3
NB&Certificates
4
Vigilance and Post-market Surveillance
5
Market Surveillance
6
Clinical Investigations/Performance Studies
IT development in progress
EUDAMED Public website

EUDAMED - Gradual roll-out

3

Amendment of Art. 34 MDR

- Modules to be released once audited and declared functional, either individually or grouped
- Procedural aspects unchanged (Independent Audit, consultation with MDCG, publication of notice in *OJ*)

Article 34

Functionality of Eudamed

1. The Commission shall, in collaboration with the MDCG, draw up the functional specifications for Eudamed. The Commission shall draw up a plan for the implementation of those specifications by 26 May 2018. ~~That plan shall seek to ensure that Eudamed is fully functional at a date that allows the Commission to publish the notice referred to in paragraph 3 of this Article by 25 March 2020 and that all other relevant deadlines laid down in Article 123 of this Regulation and in Article 113 of Regulation (EU) 2017/746 are met~~.

2. The Commission shall, ~~on the basis of an independent audit report~~, inform the MDCG when, on the basis of independent audit reports when it has verified that one or more of the electronic systems referred to in Article 33(2) are functional and ~~Eudamed has achieved full functionality and Eudamed~~ meet~~s~~ the functional specifications drawn up pursuant to paragraph 1 of this Article.

3. The Commission shall, after consultation with the MDCG and when it is satisfied that the conditions referred to in paragraph 2 have been fulfilled, publish a notice to that effect in the Official Journal of the European Union.

11

Next steps : ongoing activities and perspectives (1)

- **Legislative :**
  - Monitoring of implementation of **Regulation (EU) 2023/607**
  - **Commission proposal 2024/0021**
- **Other Initiatives:**
  - **Study on the availability of MDs/IVDs** and MDCG Task Force on capacity
  - **Study on Regulatory Governance and Innovation** in the field of medical devices (Q2 2023 – Q4 2024)
  - **COMBINE project -** challenges for combined studies (interface of the MDR/IVDR & Clinical Trials Regulation)
  - **Pilot project on scientific advice** by the EMA expert panels for certain high risk medical devices
- **Interplay of MDR/IVDR with horizontal legislation** (e.g. REACH, AI Act, EHDS,…)

Targeted evaluation

Focused targeted evaluation of MDR and IVDR to take stock and assess whether the two regulations:

- are effective, efficient and proportionate
- meet current and emerging needs
- align with other actions
- have EU added value.

Non-legislative measures

ACTIONS TO INCREASE THE CAPACITY OF NOTIFIED BODIES AND HELPING PREPARE MANUFACTURERS

Position paper by Medical Device Coordination Group identifying actions to increase notified body capacity, the access to notified bodies and manufacturer preparedness (MDCG 2022-14 position paper)

Increasing the number of notified bodies

Consortium (NoBoCap) developing actions to increase the capacity of notified bodies and the preparedness of manufacturers (trainings) and facilitating access to notified bodies, **especially for SMEs** (matchmaking platform) (EU4Health)

Supporting coordination between **notified bodies** (EU4Health)

Tailored solutions for **orphan devices**

Targeted support to SMEs through Enterprise Europe Network

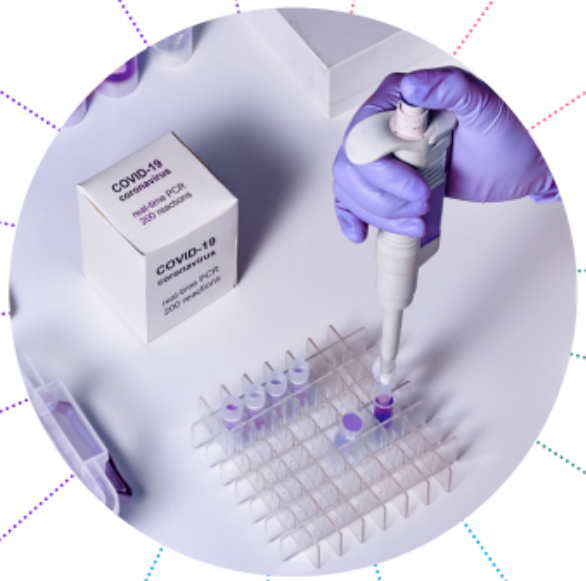
NEW: Development of further supporting tools such as **translation of nomenclatures**

SUPPORT FOR INNOVATION AND ADDRESSING SPECIAL NEEDS

Pilot on **scientific advice by expert panels for clinical development strategies** for high-risk devices

Orphan device support programme, focussed on paediatrics (EU4Health)

NEW: Additional pilots with **expert panels to support conformity assessment**



STOCK TAKING OF REGULATORY FRAMEWORK AND TRANSITION (EU4HEALTH)

Study on **governance and innovation**

Study to **monitor availability of medical devices on EU market**

NEW: Studies supporting the targeted evaluation of MDR/IVDR

SUPPORT TO REGULATORY INFRASTRUCTURE AND PROCESSES (EU4HEALTH)

Support for **European database on medical devices**

Support for **designated EU reference laboratories** (*in vitro* diagnostics)

Joint Action on **market surveillance**

NEW: **Horizon scanning** for medical devices (EU4Health)

Thank you

Nada.alkhayat@ec.europa.eu


IMDRF
International Medical Device
Regulators Forum
United States
of America
2024